



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,263	01/18/2006	Bjorn Carlsson	ASZDP01136	5249
28120	7590	05/31/2007		
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER CHONG, KIMBERLY	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 05/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,263	Applicant(s) CARLSSON ET AL.	
	Examiner Kimberly Chong	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Furthermore, under PCT Rule 13.2 the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 8, drawn to a method of identifying a test compound that modulates the expression of BHLHB2 gene comprising contacting a cell capable of expression BHLHB2 gene with a test compound and determining the level of expression of the BHLHB2 gene.

Group II, claim(s) 2, 9, drawn to a method of identifying a test compound that modulates the activity of a BHLHB2 protein comprising contacting a BHLHB2 protein with a test compound and determining the level of activity of the BHLHB2 protein in the presence of the compound.

Art Unit: 1635

Group III, claim(s) 3, 6 and 16, drawn to a method of treating a subject having CAD comprising administering an effective amount of a compound that modulates the expression of a BHLHB2 gene.

Group IV, claim(s) 3, 5 and 16, drawn to a method of treating a subject having CAD comprising administering an effective amount of an antibody specific for protein BHLHB2.

Group V, claim(s) 7 and 17, drawn to a pharmaceutical composition comprising the compound wherein the compound modulates the expression of BHLHB2 gene.

Group VI, claim(s) 7 and 17, drawn to a pharmaceutical composition comprising the compound wherein the compound binds to and modulates the activity of a BHLHB2 protein.

Group VII, claim(s) 10 and 19, drawn to a method for determining if a BHLBH2 gene has an altered level of gene expression comprising comparing the level of BHLBH2 gene expression of a patient having CAD with a control cell and determining the level of expression in both cells.

Group VIII, claim(s) 11 and 20, drawn to a method for determining the level of a BHLBH2 protein in a CAD patient compared to a control, comprising comparing the level of BHLBH2 gene expression of a patient having CAD with a control cell and determining the level of expression in both cells.

Group IX, claim(s) 18, drawn to a method of identifying other components of the CAD biochemical pathway of which BHLHB2 is a component.

Art Unit: 1635

The inventions listed as Groups I, III, V and VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of Groups I, III, V and VII is a compound that modulates the expression of BHLHB2 gene. The compound cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Bek et al. teach an antisense compound targeted to a gene encoding Stra13, which is a BHLHB2 gene (see page 3).

The inventions listed as Groups I, III, V and VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of II, IV, VI and VIII is a compound that binds to and modulates the activity of a BHLHB2 protein. The compound cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Giatromanolaki et al. teach an antibody targeted to a DEC 1 (Stra13) protein, which is a BHLHB2 gene (see page 223).

The inventions listed as Groups I, III, V and VII, Groups I, III, V and VII and Group IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups I, III, V and VII is an antisense compound that regulates BHLHB2 gene expression. The special

Art Unit: 1635

technical feature of Groups I, III, V and VII is a compound that binds to and modulates the activity of a BHLHB2 protein, which is not present in Groups I, III, V and VII. The special technical of group IX is a component of the CAD biochemical pathway which is not necessarily the compounds of groups I-VIII.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

Art Unit: 1635

problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

KC
Examiner
Art Unit 1635

/Sean McGarry/
Primary Examiner AU 1635